Home diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome: Technology Assessment

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Key questions (simplified)

• Does baseline severity of OSAHS predict response to CPAP or clinical outcomes?
• How do portable monitors compare with facility-based PSG in diagnosing OSAHS?
• What effects do technologist support and automated scoring have on the diagnostic ability of portable monitors?
• What are the complications, harms and adverse events pertinent to sleep studies?
• What are the errors and data loss rates in different settings in portable monitors versus lab-PSG?
Methods

Systematic review of the literature to address the key questions

• Electronic MEDLINE searches and perusal of reference lists from relevant papers

• Electronic searches of the FDA database of adverse events secondary to medical device use (1992-2006)
Study eligibility criteria

We included prospective studies that addressed the questions of interest
[Details are given in the report]
Modified ASDA criteria to classify portable monitors

<table>
<thead>
<tr>
<th>Type or Level</th>
<th>Portability</th>
<th>Indicative $N_{\text{channels}}$</th>
<th>$\geq 2$ airflow/effort channels</th>
<th>Identifies sleep/wake</th>
<th>AHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Facility-based</td>
<td>~14-16</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>II</td>
<td>Portable</td>
<td>$\geq 7$</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>III</td>
<td>Portable</td>
<td>$\geq 4$</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>IV$_3^+$</td>
<td>Portable</td>
<td>$\geq 3$</td>
<td>No</td>
<td>Yes(?)</td>
<td>No</td>
</tr>
<tr>
<td>IV$_2^-$</td>
<td>Portable</td>
<td>~1-2</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Literature flow

3575 citations from electronic searches and perusal of references

321 publications obtained in full text and reviewed

226 excluded:
- No relevant data (n=157)
- Retrospective (n=22)
- Small sample* (n=16)
- Duplicate (n=5)
- Combination of reasons (n=26)

95 publications finally eligible
Question B1. Ability of baseline AHI to predict outcomes

- We did not identify any studies that associated the baseline severity of OSAHS (AHI) with changes in clinical outcomes such as mortality and CVD, after CPAP treatment
- Response to CPAP or CPAP compliance: 2 RCT and 3 prospective cohorts
- Changes in QoL scores: 2 RCT
- Changes in physiological measurements: 4 cohorts
Question B1. Synopsis

- Baseline AHI/RDI is only modestly associated with response to CPAP use or adherence to CPAP, QoL scores and physiological outcomes.
- All associations were assessed in people with high AHI/severe disease.
- These data do not answer whether facility-based PSG is generally useful in the management of people who are suspected for OSAHS.
Question B2. Comparison of portable monitors vs lab-PSG

75 eligible studies

• Assessment of concordance with lab-PSG

• Assessment of ability to predict AHI suggestive of OSAHS in lab-PSG
  – AHI>15 events/hour of sleep (main analysis)
  – AHI>10 and >20 events/hour of sleep (secondary analyses)
Assessing concordance (I)
Assessing concordance (II)
Bland-Altman plot

![Bland-Altman plot diagram](image)
Interpretation of diagnostic accuracy studies
Studies of portable monitors

- Type II
  - Home (n=2)
  - Sleep unit (n=3)
- Type III
  - Home (n=8)
  - Hospital (n=2)
  - Sleep unit (n=15)
- Type IV$_{3+}$
  - Home (n=5)
  - Hospital (n=1)
  - Sleep unit (n=15)
- Type IV$_2^-$
  - Home (n=6)
  - Sleep unit (n=26)
Type III, home setting
Type III monitors

Home setting

Lab setting (manual)

Lab–PSG AHI cutoff:
- ○ 10 events/h
- ■ 15 events/h
- ▲ 20 events/h
Synopsis for question B2

• For all monitor types, Bland-Altman analyses suggest that measurements with portable monitors and facility-based PSG are not interchangeable.

• Discrepancies are larger for large values of AHI/RDI.

• Nevertheless, classification to “high” and “low” AHI/RDI can still be good (e.g., both measurements are above the diagnostic cutoff, although the actual values may differ greatly).
Synopsis for type II

- Based on limited data, type II monitors may identify AHI >15 events/hour in lab-based PSG with high diagnostic ability
Synopsis for type III

• Type III monitors may identify AHI suggestive of OSAHS (>15 events/hour) with high diagnostic ability

• Overall, diagnostic ability appears to be higher for studies conducted in the lab setting, and for studies with manual scoring of the portable monitor recordings
Synopsis for type IV

- Studies of type IV monitors assessing 3 or more bioparameters showed high diagnostic ability to identify AHI >15 events/hour in lab-based PSG.
- The same was true for studies of type IV monitors assessing 1 or 2 bioparameters, *at least for selected cutoffs* of the portable monitor measurements.
- Studies in the lab setting appeared to have better diagnostic ability than studies in the home setting.
Applicability to the Medicare population (I)

Studies that assessed the diagnostic ability of portable monitors were conducted on participants that are predominantly

- Young (~50 years old on average)
- Male
- Obese
- Without comorbidities that may affect sleep

Moreover, they are conducted by specialists who are experienced in sleep medicine
Applicability to the Medicare population (II)

In the Medicare population one may expect lower specificity of portable monitors (relatively more false positives)

- Conditions such as cardiac insufficiency and atrial flutter may exhibit Cheyne-Stokes breathing patterns
- These are not differentiated from OSAHS by some portable monitors

In addition, widespread use of the technology by health providers not familiar with the disease will probably result in worse overall diagnostic performance
Question B2a. Role of technologist support and patient education in the home setting

- For studies in the home setting, there is no direct evidence on whether and to which extent these factors may affect the comparison of portable monitors with facility-based PSG
Question Q3a. Comparison of manual and automated scoring

• In studies that assessed both scoring methods, manual scoring or manual editing of automated scoring seems to be superior to automated scoring to identify AHI>15 in facility-based PSG

• In considering this, one should keep in mind that scoring algorithms differ across monitors, and evolve with software versions
Question B3b. What errors related to automated and manual scoring are reported?

- We did not identify any detailed data on the specific types of errors that are related to automated or manual scoring.
- No robust conclusions can be drawn.
Question B4. For studies of portable monitors in the home setting, what errors are related to unattended use?

- No studies linked directly unattended usage in the home setting with specific errors.
- However, indirect data are compatible with reduced error rate when some sort of feedback (e.g., alarm) is provided to the user, or when data were remotely sent to a technologist in the lab.
Question B5. Comparison of complications harms and adverse events in lab-based PSG and portable monitors

FDA database on adverse events of medical devices (1992-Dec 2006):

- The reported adverse events pertained to burns (electrical, chemical, thermal), possible allergic reactions and eye irritations after showering
Complications, harms and adverse events (II)

Among 16,084 facility-based PSG studies in 17 US centers

• 1 death after 2 weeks: 0.0062% (95% CI: 0, 0.019%)
• 28 events prompting immediate attention: 0.17% (95% CI: 0, 0.24%)
• 28 alarming events identified post-hoc by the scoring team (ventricular arrhythmias)
Question B6. Rates of data loss in sleep studies

![Graph showing rates of data loss in sleep studies](image-url)
Modeling different diagnostic strategies

- No study directly compared several plausible strategies for the diagnosis of OSA and CPAP treatment initiation
- Decision analytic techniques used to compare different strategies
- In this case, we did not perform a full decision analysis (utility not incorporated in analysis)
- Calculated probability profile for various strategies
### Overview of modeled strategies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Diagnosis</th>
<th>CPAP level titration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>[None]</td>
<td>[None on CPAP]</td>
</tr>
<tr>
<td>2</td>
<td>Lab-PSG*</td>
<td>Lab-PSG*</td>
</tr>
<tr>
<td>3</td>
<td>Split-night PSG*</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Home PM</td>
<td>Split-night PSG*</td>
</tr>
<tr>
<td>5</td>
<td>Home PM</td>
<td>Home autoCPAP</td>
</tr>
<tr>
<td>6</td>
<td>[None]</td>
<td>[All start on CPAP]</td>
</tr>
</tbody>
</table>
Assessed outcomes

• Proportion starting CPAP treatment
• Mean time to diagnosis
• Mean time to CPAP initiation*

Among
  – All participants in the cohort
  – People with OSAHS
  – People without OSAHS

*meaningful only among those with OSAHS (i.e., time in potentially “high-risk” states)
Population, models and time horizon

- Hypothetical cohort of 100,000 people who are clinically suspected for OSAHS
  - One cohort of 50 year old people*
- Markov processes
- Time horizon of 2 years using 1 week cycles

* Sensitivity analyses used assumptions for older adults (~70 year old)
Assumptions pertinent to all strategies

• OSAHS severity remains stable
• The risk of death is not modeled
• Co-morbidities, co-existing disorders or health conditions other than OSAHS are not explicitly modeled
Implicit assumptions

- Benefits of treatment are assumed for those with true positive diagnoses
- Avoidance of unnecessary treatments to those with true negative diagnoses
- Potential harm and unnecessary costs to those with false positive or false negative diagnoses
Challenges in obtaining transition probabilities

• All estimates on diagnostic ability of portable monitors are from studies on ~50 year olds, mostly obese, mostly males, without co-morbidities

• Translating transition probabilities to a hypothetical cohort of Medicare beneficiaries is based on assumptions
Prevalence of OSAHS among people suspected for OSAHS

• Operational definition of OSAHS as AHI>15 events/hour of sleep in lab-PSG

• Meta-analysis of 30 studies:
  – 54% (95% CI: 48, 60%)
  – Range for sensitivity analyses (~IQR): 25% to 75%

• Assumed to be lower for the sensitivity analysis among 70 year old people (i.e., 27%)
  – Dissociation of clinical symptoms and OSAHS in older age
Sensitivity and Specificity of Portable Monitor (from bivariate meta-analysis)

For ~50y

- Sensitivity (95% CI): 90% (83, 94%)
- Specificity (95% CI): 84% (68, 93%)

- We assumed a lower specificity among older adults (70%)
Proportion starting on CPAP

Percent (%)

[Diagram showing bar chart with bars for 'middle aged (50y)' and 'older (70y)']

1  2  3  4  5  6

middle aged (50y)  older (70y)
Proportion starting on CPAP, among patients with OSAHS

![Bar chart showing the proportion of patients starting on CPAP among those with OSAHS, categorized by age groups (middle aged 50y and older 70y). The chart indicates the percentage of patients starting on CPAP over time with distinct bars for each age group.]
Proportion starting on CPAP, among people without OSAHS
Time to first AHI/RDI measurement (as % of the 2 years of follow-up)
Time to CPAP initiation (as % of the 2 years of follow-up)
Summary (I)

Middle aged people (~50y):
• The proportion of people who are expected to initiate CPAP treatment is roughly similar across the 4 strategies that employ testing for OSA (+/-10%)
• This seems to be fairly robust across sensitivity analyses

 Older adults (~70y)
• Diagnosis and CPAP level titration at home (strategy 5) is expected to result in 30% false positive diagnoses among OSA patients (and increase the numbers in the whole cohort)
Summary (II)

For both cohorts (~50y & ~70y):
- Time to first AHI/RDI measurement is practically negligible for strategies where home monitoring is used in the diagnostic part
- When the diagnostic part is done in the lab, the mean time to first AHI/RDI measurement is approximately 26 weeks
- This mean delay is very sensitive to the corresponding sensitivity analysis
Summary (III)

For both cohorts (~50y and ~70y)

- Time to CPAP treatment initiation among those with OSA
  - ~27 weeks when all people are diagnosed in the lab (either with full-night or split-night studies) (strategies 2 and 3)
  - ~15 weeks when screening with home monitors is done (strategy 4)
  - Negligible with a home-based approach (strategy 5)

- Sensitive to assumptions on mean sleep lab queue length, diagnostic characteristics of monitors